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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,048	03/31/2004	Heather Allen	07500.0416US01	5733

23552 7590 06/16/2005

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EXAMINER	
CHIN, BRAD Y	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,048	ALLEN, HEATHER	
	Examiner	Art Unit	
	Brad Y. Chin	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/22/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 5, 7, 9 and 10 are objected to because of the following informalities:

In claim 5, line 2, Applicant should amend the word "it" to "the treated items"

In claim 7, line 4, Applicant should amend the word, "stage" to "state".

In claim 9, line 2, Applicant should amend the word, "discernable" to discernably".

In claim 10, line 6, Applicant should amend the article, "the" to "a".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 1 provides for the use of a material which includes ethylene dioxide for the purpose of providing a substantially DNA free item, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Matthews et. al. [U.S. Patent No. 5,209,902].

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). Similarly, the claiming of a new use, new function, or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best,* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). As acknowledged by Applicant in his specification (see page 7, lines 18-19), sterilization processes involving contacting items with ethylene oxide are extremely well known. The claimed products and methods do not appear to describe any structure or step(s), respectively, which is not already known in the prior art; accordingly, it would be inherent that the prior art references result in products that are substantially DNA free.

Regarding claims 1-3, Matthews et. al. teach the use of a material, which includes ethylene oxide for the purpose of providing a substantially DNA free item; an item, which is substantially free of DNA; and an item, which is substantially DNA free due to treatment involving contacting the item with a mixture including ethylene oxide (See col. 1 line 60 to col. 2,

line 5 – use of microwave energy in conjunction with ethylene oxide gas for sterilization; See col. 2, lines 6-35 – a strong alternating electromagnetic field tends to orient with the applied field causing a degree of molecular disturbance. It has been found that microwaves exert a biocidal effect distinct from that of thermal energy, and it is believed that this may result from their effect on metabolic chemistry, possibly by causing alternations in cell membrane permeability, or by altering the pH (acidity) of the cellular environment, or by modifying weak chemical bonds between cellular macromolecules. It is also believed that a very advantageous non-thermal biocidal effect of microwaves lies in the degree of absorption of microwave energy by key molecules such as DNA. For these reasons it is believed that microwave irradiated microorganisms are less viable and more susceptible to destruction by ethylene oxide gas. A mode of action involving direct effect upon cellular DNA particularly favors the synergistic use with ethylene oxide gas, which also exerts a direct effect upon DNA [i.e., use of microwave energy in conjunction with ethylene oxide gas to sterilize articles in addition to provide a substantially DNA free item, e.g. disrupting the cellular structure of DNA and inactivating such DNA by a biocidal effect]; See col. 1, lines 36-45 – biocidal efficacy of ethylene oxide on DNA; See col. 2, lines 48-51 – ethylene oxide gas has sometimes been mixed with Freon or carbon dioxide).

Regarding claim 4, Matthews et. al. teach a method of treatment in which an item has a first-pretreatment state in which it has DNA associated with it and has a second post-treatment state in which the item is substantially free of DNA, the treatment involving contacting the item with a mixture including ethylene oxide (See col. 8, lines 35-50 – pre-treatment of the articles followed by application of ethylene oxide, where prior to the application of ethylene oxide, the article would have DNA associated with it and be substantially free of DNA upon application of ethylene oxide gas to the chamber under vacuum).

Regarding claim 6, Matthews et. al. teach the method in which the treatment involves contacting the item with a first volume including ethylene oxide and with a second volume of ethylene oxide (See col. 8, lines 44-50 – ethylene oxide is admitted under sub-atmospheric partial vacuum conditions and sterilization continues either for a fixed time or until pre-determined parameters are reached as determined by the sensors on the equipment).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 5 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et. al., as applied above in paragraph 3, and further in view of Gill [WO 01/79541].

"The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim

patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). As acknowledged by Applicant in his specification (see page 7, lines 18-19), sterilization processes involving contacting items with ethylene oxide are extremely well known. The claimed products and methods do not appear to describe any structure or step(s), respectively, which is not already known in the prior art; accordingly, it would be inherent that the prior art references result in products that are substantially DNA free.

Regarding claim 5, Matthews et. al. teach the method as described above in paragraph 3, but fail to teach the method further includes analysis of one or more such treated items to establish the amount of DNA associated with the treated items after treatment. Gill teaches the method for obtaining information about DNA analysis of samples by comparing results with reference results to determine a probability of a match between a test sample and each of the reference samples by calculating likelihood ratios (See pages 26-44). Gill determines a particular level of DNA present by measuring or identifying the DNA allele drop, which can be correlated or associated with a DNA clean environment (See pages 26-44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Gill with the method of treating an item with ethylene oxide, as taught by Matthews et. al., because the process of Gill would exhibit and confirm whether the treatment of the articles by the process of Matthews et. al. was successful, indicating the biocidal efficacy of ethylene oxide gas on the DNA contained on the article.

Regarding claim 10, Matthews et. al. teach a method for producing items in the form of one or more products, the method including a treatment in which the items are contacted with ethylene oxide (See col. 8, lines 44-50 – ethylene oxide is admitted under sub-atmospheric partial vacuum conditions and sterilization continues either for a fixed time or until pre-determined parameters are reached as determined by the sensors on the equipment).

Matthews et. al. fail to particularly teach that the method includes forming one or more second products, where one or more of the first products of the process is provided to a user and one or more of the second products of the process is analyzed to establish whether the second product has DNA associated with it in a second post-treatment state. Gill teaches the method for obtaining information about DNA analysis of samples by comparing results with reference results to determine a probability of a match between a test sample and each of the reference samples by calculating likelihood ratios (See pages 26-44). Gill determines a particular level of DNA present by measuring or identifying the DNA allele drop, which can be correlated or associated with a DNA clean environment (See pages 26-44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the method of Gill into the method of Matthews et. al. for producing one or more first products and one or more second products because the first products could be used by a user while the second products are being testing, using the method of Gill, to determine the efficacy of the application of ethylene oxide to the articles produced – articles that are produced upon application of and being sterilized by ethylene oxide.

Regarding claim 11, Matthews et. al. fail to particularly teach that the first products of the process are the same as the second products of the process, and only differ in the use to which they are put after treatment. As discussed in claim 10, Gill teaches the use of samples or products to test the efficacy of an application of ethylene oxide on an article by measuring or identifying the DNA allele drop, which can be correlated or associated with a DNA clean environment (See pages 26-44). It would have been obvious to one of ordinary skill in the art at the time the invention was made that the applying the method of Gill to the method and products produced by Matthews et. al., provides for a first set of products, to be used by a user, and a

second set of products, to be tested, which are the same products produced, and only differ in the use to which they are put after treatment, by the user and for testing purposes.

5. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orelski [U.S. Patent No. 4,291,122] in view of Manning [U.S. Patent No. 4,436,819].

As acknowledged by Applicant in his specification (see page 7, lines 18-19), sterilization processes involving contacting items with ethylene oxide are extremely well known. The claimed products and methods do not appear to describe any structure or step(s), respectively, which is not already known in the prior art; accordingly, it would be inherent that the prior art references result in products that are substantially DNA free.

The recitation, of verifying the substantially DNA free status of an item, has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Regarding claim 7, Orelski teaches a method for a biological indicator, the method teaches providing a biological, where the biological indicator has a first state and a second state, the biological indicator being converted to the second state by contact with a material including ethylene oxide, the state of the biological indicator being checked to ensure it is in the second state, i.e. the efficacious process of applying ethylene oxide to the sterilization of an item (See col. 4, lines 1-4 and 15-27 – the biological indicator in a first state at the moment it is placed in a sterile chamber and a second state where a color change occurs indicating a yellow

color for a positive test indicating spore growth and an unsatisfactory sterilization or a red color indicating no more spore growth and a satisfactory sterilization), but fails to teach providing the item within a package and associating a biological indicator in association with the package. Manning teaches an ethylene oxide process, where the device or indicator is placed in a sterilizing environment, usually in accompaniment, i.e. in a package, with articles being sterilized. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teaching of Manning into the process of Orelski because placing the indicator of Orelski into a package containing an article that is treated with ethylene oxide functions to indicate the efficacious effect of ethylene oxide on the article to be sterilized.

Regarding claim 8, Manning teaches the biological indicator inside packaging, where the biological indicator is isolated from the item in terms of DNA transfer from the biological indicator to the item (See col. 2, line 64 – col. 3, line 15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teaching of Manning into the process of Orelski for determining efficacy of ethylene oxide on an article and isolating the biological indicator from the item in terms of DNA transfer from the indicator to the item because such an orientation would prevent the contamination of the article by transfer of DNA that might be contained on the biological indicator.

Regarding claim 9, Orelski teaches the method in which the biological indicator in the second state is discernably different from the biological indicator in the first state (See col. 4, lines 1-4 and 15-27 – the biological indicator in a first state at the moment it is placed in a sterile chamber and a second state where a color change occurs indicating a yellow color for a positive test indicating spore growth and an unsatisfactory sterilization or a red color indicating no more spore growth and a satisfactory sterilization).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sun (John) Kim, can be reached at 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc
June 8, 2005

JOHN KIM
SUPERVISORY PATENT EXAMINER